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The Honorable Sherry R. Fallon, U.S.M.J.
J. Caleb Boggs Federal Building
844 N. King Street, Unit 14 - Room 6100
Wilmington, DE 19801-3555

REDACTED
PUBLIC VERSION

Re: *Orexo AB and Orexo US, Inc. v. Actavis Elizabeth LLC*, C.A. No. 14-829 (SLR)(SRF)

Dear Judge Fallon:

We submit this letter on behalf of Defendant Actavis Elizabeth LLC in response to Orexo's request that the Court compel the production of certain samples of "intermediates" and raw materials of Actavis' ANDA product (D.I. 116). As Actavis has explained to Orexo, the "intermediates" it seeks do not exist, and Orexo already has access to the raw materials, which are irrelevant but commercially available from suppliers that Actavis long ago identified to Orexo. For the reasons explained below, the Court should deny Orexo's request.

I. Actavis Has Already Agreed To Produce Samples Of Its ANDA Product.

Actavis long ago agreed to produce samples of its ANDA product to Orexo. (Ex. 5[1] at 2 (stating on April 29, 2015 that Actavis will produce 200 tablets of each dosage strength). Indeed, had Orexo not chosen to use an overseas laboratory to receive the samples, it would already have them in its possession. Instead, as a result of Orexo's choice, Actavis was required to ship the samples (which contain a controlled substance) overseas, which in turn required securing government approval in both the receiving (UK) and shipping (US) countries. (*See* Ex. 7 at 3.) Securing those approvals has been an unavoidably slow process. Actavis takes issue with Orexo's insinuation that Actavis has been dilatory. Actavis *promptly* requested the necessary export permit upon Orexo's provision of the required paperwork. (*Id.*) Actavis has no control over the time it takes the DEA to issue the permit. On the other hand, Orexo had complete control over which testing laboratory it selected.

II. The Raw Materials Orexo Seeks Are Available From Commercial Suppliers.

Actavis has repeatedly told Orexo that, although the raw materials it seeks are of no relevance to this litigation beyond the finished product that Actavis will produce, Orexo can

[1] Unless otherwise noted, exhibit citations herein refer to the exhibits attached to Orexo's letter brief (D.I. 116).

easily acquire them itself from any number of commercial vendors, including the specific suppliers for Actavis. (*E.g.*, Ex. 5 at 2.) Actavis has also repeatedly explained to Orexo that [redacted] (*E.g.*, Ex. 8 at 1; *see also* Ex. 7 at 3.) Once again, Actavis can and will produce its finished ANDA product—the actual product that Orexo is accusing of infringement and which contains the buprenorphine that Orexo seeks.

Orexo's rationale for why it might require raw material samples does not explain why the burden of securing those samples should be shifted from Orexo to Actavis. It should not. Orexo, as the commercial manufacturer of Zubsolv®—the reference brand product for Actavis' ANDA product—is plainly capable of acquiring (and undoubtedly already has) the materials necessary to make Zubsolv®. In fact, Orexo says that it requires samples simply as "reference material" in order to "identify and compare the location of materials relative to each other in Actavis's tablets[.]" (D.I. 116 at 2.) But that rationale does not explain why Orexo cannot purchase the raw materials itself or use the raw materials it already has as a "reference." Orexo's second explanation is that it may perform "blending tests with these samples" to determine whether they adhere to one another. (*Id.*) Again, Orexo gives no reason why Actavis should be compelled to provide these ingredients when Orexo already has—or can easily acquire—the materials itself.

Orexo's only explanation for why *Actavis* should have to purchase and provide these commercially available raw material samples is to say that this method "avoids arguments regarding the representative nature of the samples." (*Id.*) That assertion rings hollow. Orexo knows exactly what ingredients Actavis uses and knows exactly where Actavis purchases them. Indeed, Orexo's argument is belied by its own insistence that Actavis purchase ***new*** raw materials from its suppliers and provide those materials to Orexo. (*See id.* at 4.) If such samples would supposedly be "representative" when Actavis purchases them, they would be just as "representative" if Orexo were to purchase them.

Not only has Orexo failed to articulate why it cannot use its own materials or purchase them from a supplier, Orexo has not even attempted to subpoena the materials from the supplier companies Actavis identified in its ANDA ***nine months ago***. It is absolutely incorrect for Orexo to now assert that "Actavis refused" to "assist in obtaining samples from suppliers." (*Id.*) What Actavis refused to do was send a letter *drafted by Orexo* asking Actavis' suppliers to immediately produce samples of materials at Actavis' expense. (Ex. 8 at 1-2; *see also* Ex. 1 at exhibit B.) In reality, Actavis indicated that it would be happy to contact its suppliers and encourage their compliance with any reasonable subpoena issued by Orexo. (Ex. 8 at 1-2.) Orexo has not served any such subpoena and has refused to consider any alternative means of acquiring the materials. Once again, the expense of obtaining commercially-available samples for Orexo's use should not be borne by Actavis, and Orexo cites no law for that proposition. Indeed, the Federal Rules of Civil Procedure are clear that Orexo may only seek discovery from Actavis of those "items in [Actavis'] ***possession, custody, or control***[.]" Fed. R. Civ. P. 34(a)(1).

III. The Raw Materials Are Irrelevant, But Actavis is Nevertheless Willing to Produce a Reasonable Quantity of a Reasonable Subset of Them.

Orexo has accused Actavis' ANDA product of infringement and Actavis has agreed to

produce samples of that product. No more should be necessary in order for Orexo to assess infringement. Nevertheless, Orexo contends that the raw materials are necessary in order to evaluate whether Actavis' ANDA product meets certain limitations of the asserted claims which require that the buprenorphine have certain relationships with "carrier particles." (D.I. 116 at 1.) Specifically, Orexo apparently intends to evaluate whether, in Actavis' ANDA product, the particles of buprenorphine are "presented at," "presented upon," and/or "adhered to" the surfaces of the carrier particles. (*Id.*)

That determination depends on the placement of the ingredients in ***Actavis' ANDA product*** and is not informed by the raw materials themselves. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248-49 (Fed. Cir. 2000) (the infringement inquiry "is properly grounded in the ANDA application and the extensive materials typically submitted in its support"). Nevertheless, Actavis has attempted to reach a compromise with Orexo. Actavis has repeatedly told Orexo that it will consider requests for a reasonable quantity of a reasonable subset of raw materials. (Ex. 7 at 3; Ex. 8 at 1; Ex. 13 at 1.) To this end, Actavis offered to produce a reasonable quantity of the excipients mannitol and magnesium stearate. (Ex. 7 at 3.) But Orexo has refused to accept anything less than 50 grams of each and every ingredient in Actavis' ANDA product, including things like lemon flavoring and menthol flavoring that have absolutely nothing to do with infringement issues in this litigation. (*See* Ex. 4 at 17.)

Despite repeated requests from Actavis that it do so, Orexo has refused to reduce the number of materials for which it requests samples, refused to reduce the amount of each sample it seeks, and has refused to even explain *why* it needs each ingredient in the requested amount. The raw materials are not relevant, and Orexo's effort to manufacture a discovery dispute by an utter refusal to entertain reasonable accommodations should be rejected.

IV. The Requested "Intermediates" Are Irrelevant And Actavis Has None To Produce.

In addition to raw materials, Orexo seeks production of "intermediates", i.e., samples taken from various incomplete stages of manufacture of Actavis' ANDA product. (D.I. 116 at 2.) However, once again it is Actavis' ANDA product that is accused of infringement in this case, not its "intermediates." Actavis is prepared to produce samples of the ANDA product as soon as the requisite DEA permits are issued.

However, Actavis has no "intermediates" of its ANDA product to produce. As Actavis has repeatedly told Orexo: Actavis does not and is not required to maintain samples of intermediates. (Ex. 5 at 2; Ex. 13 at 1.) Actavis cannot produce what it does not have.

V. Orexo's Belated Effort To Seek Discovery About A Different ANDA Product Is Improper.

Orexo argues that after it issued its discovery requests, Actavis *did* possess samples of the raw materials and intermediates, but either failed to retain such samples or refused to produce them. (D.I. 116 at 3-4.) This allegation is incorrect.

In making that argument, Orexo points to the fact that Actavis prepared batches of ***a different*** product in January 2015 that contains the same or similar ingredients (in different

amounts) as the accused ANDA product. (*Id.* at 3.) What Orexo fails to mention is that Orexo ***never requested those materials***, that the materials are irrelevant, and that Actavis was under no obligation to retain or produce them.

In its discovery requests, Orexo asked for samples of Actavis' ANDA product, the raw materials it contains, and its intermediates. (Ex. 4 at 17-18.) Orexo specifically defined the "ANDA product" as "any drug products described in Abbreviated New Drug Application No. 20-6258, including but not limited to the 1.4mg/0.36mg and 5.7mg/1.4mg buprenorphine hydrochloride/naloxone hydrochloride." (Ex. A to this letter at 20, ¶ 3.) There is absolutely no dispute that the product Actavis manufactured in January 2015 is ***not*** "described in Abbreviated New Drug Application No. 20-6258" and is ***not*** Actavis' ANDA product at issue in this case. Realizing this, Orexo for the very first time on September 10, 2015—a mere five days ago—belatedly wrote a letter attempting to expand its discovery requests to include products other than those at issue in the case. (Ex. 1 at 2.) Orexo now claims to be seeking "materials that meet the specifications in Actavis' ANDA No. 206258, even if they are not … specifically designated for" the ANDA product. (*Id.*) Again, that is not what Orexo asked Actavis to produce when it issued its discovery requests over 9 months ago. (Ex. A to this letter at 20, ¶ 3.) Orexo's new request regarding a different product is not ripe for review in this discovery conference.

Moreover, it is entirely improper and misleading for Orexo to seek to expand the scope of its discovery requests at the eleventh hour and then accuse Actavis of "fail[ing] to preserve" evidence. (D.I. 116 at 4.) In reality, Actavis has been entirely forthright throughout this process, has agreed to produce samples of its ANDA product, has told Orexo the reasons it cannot provide samples of the buprenorphine and intermediates (i.e., it does not have any to give), agreed to produce a more limited set of raw materials samples if Orexo would explain exactly what it requires and why (which Orexo refused to do), and told Orexo exactly where it could acquire samples to the extent it did not already know. Orexo has declined all of these opportunities to acquire the samples it allegedly needs and has instead manufactured a dispute where none exists. Finally, Actavis is under no obligation to purchase material for purposes of discovery in this case, and should not be required to do so. (*See* Fed. R. Civ. P. 34(a)(1) ("items in the responding party's ***possession, custody, or control***[.]").

For these reasons, Actavis respectfully requests that the Court deny Orexo's request.

Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)

cc: All counsel of record (via ECF & email)